



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

07/JAN/2000

MEMORANDUM

Subject: EPA Reg. No.: 499-304 Whitmire Optem PT 600
DP Barcode: D260271
Case No: 192492
PC Code: 128831

From: Eugenia McAndrew, Biologist *EM SCR*
Technical Review Branch
Registration Division (7505C)

To: Linda Deluise, PM Team 03
Insecticide Branch
Registration Division (7505C)

Applicant: Whitmire Micro-Gen Research Laboratories, Inc.
3568 Tree Court Ind. Blvd.
St. Louis, Mo 63122

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>		<u>% by wt.</u>
128831	Cyfluthrin	6.0
<u>Inert Ingredient(s):</u>		<u>94.0</u>
Total:		100.0%

ACTION REQUESTED: PM requests review of primary eye and primary skin irritation studies for revised alternate Confidential Statement of Formula for EPA Reg. 499-304, Whitmire Optem PT 600.

Inert ingredient information may be entitled to confidential treatment

BACKGROUND: Whitmire Micro-Gen has submitted a primary eye irritation study (MRID # 449345-01) and a primary skin irritation study (MRID # 449345-02) for EPA Reg. No. 499-304, Whitmire Optem PT 600, as requested by TRB. Previously, in a memo dated May 13, 1999, TRB evaluated an alternate formulation of the product in a CSF dated January 15, 1999 which contained the new inert [REDACTED] TRB determined that acute toxicity data could be bridged between the original and the new formulations but that due to the added toxicity of the new inerts, primary eye and skin irritation studies must be conducted on the new formulation. The registrant was given a conditional approval for the new formulation pending the submission of these two studies which are the subject of this memo.

RECOMMENDATIONS: The two studies have been reviewed and are classified as acceptable.

The revised acute toxicity profile for EPA Reg. No. 499-304 is obtained from an Agency memo dated July 2, 1991 and from the results of the two studies reviewed in this memo.

acute oral toxicity	IV	
acute dermal toxicity	III	
acute inhalation toxicity	waived	
primary eye irritation	III	acceptable
primary skin irritation	III	acceptable
dermal sensitization	Not a sensitizer	

LABELING: Based on the new toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System. The registrant indicated in a letter dated October 1, 1999 that "the labeling on file at the Agency for the subject product includes category III language."

Date: 01/06/00 LABEL REVIEW SYSTEM

ID # 000499-00304 WHITMIRE OPTEM PT 600

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Harmful if absorbed through skin. Causes moderate eye irritation.
Avoid contact with eyes, skin or clothing. Wash hands before eating,
drinking, chewing gum, using tobacco or using the toilet.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (870.2400)

Product Manager: 03
MRID No.: 44934501

Reviewer: Eugenia McAndrew
Study Completion Date: September 20, 1999
Study No.: 3430.37

Testing Facility: Springborn Laboratories, Inc., Spencerville, Ohio
Author: Deborah A. Douds, M.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: TC-62, Alternate Formula 11599; Lot No. 99081; 5.88% Cyfluthrin; beige liquid

Dosage: 0.1 mL

Species: Rabbit; New Zealand white

Age: Adult

Weight: 2.8 - 3.4 kg

Source: Myrtle's Rabbitry, Thompson Station, TN

Conclusion:

1. **Toxicity Category** III
2. **Classification:** Acceptable

Procedure (Deviations from 870.2400): None

Unwashed eyes:

Observations	Number "positive"/number tested			
	Hours			
	1	24	48	72
Corneal Opacity	0/6	0/6	0/6	0/6
Iritis	2/6	0/6	0/6	0/6
Conjunctivae:				
Redness*	3/6	3/6	0/6	0/6
Chemosis*	0/6	0/6	0/6	0/6
Discharge*	0/6	0/6	0/6	0/6

*Score of 2 or more required to be considered "positive."

Summary: At one hour after installation, iritis was observed in 2/6 eyes and redness in 3/6 eyes. The iritis cleared by 24 hours but the redness persisted in 3/6 eyes through 24 hours. All irritation cleared by 48 hours.

DATA REVIEW FOR PRIMARY DERMAL IRRITATION TESTING (870.2500)

Product Manager: 03
MRID No.: 44934502

Reviewer: Eugenia McAndrew
Study Completion Date: August 6, 1999
Study No.: 3430.38

Testing Facility: Springborn Laboratories, Inc., Spencerville, Ohio
Author: Deborah A. Douds, M.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: TC-62, Alternate Formula 11599; Lot No. 99081; 5.88% Cyfluthrin; beige liquid

Dosage: 0.5 mL

Species: Rabbit; New Zealand White males

Age: Adult

Weight: Not reported

Source: Myrtle's Rabbitry, Thompson Station, TN

Conclusion:

1. **Toxicity Category:** III
2. **Classification:** Acceptable

Procedure (Deviations from 870.2500): None

Results: PDIS = 2.3 All rabbits showed well-defined erythema and very slight to slight edema at one hour after patch removal. At 72 hours, 5/6 rabbits showed very slight to well-defined erythema with no edema. All irritation cleared by day 7. Superficial lightening was observed at 4/6 test sites.

ACUTE TOX ONE-LINERS

1. DP BARCODE: D260271
2. PC CODE: 128831
3. CURRENT DATE: 07/JAN/2000
4. TEST MATERIAL: TC-62, Alternate Formula 11599; Lot No. 99081; 5.88% Cyfluthrin; beige liquid

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Primary eye irritation/rabbit Springborn Laboratories, Inc. 3430.37/9-20-99	44934501	Slight irritant; iritis in 2/6 eyes and redness in 3/6 eyes at one hour after installation; redness persisted in 3/6 eyes through 24 hours. All irritation cleared by 48 hours	III	A
Primary skin irritation/rabbit Springborn Laboratories, Inc. 3430.38/8-6-99	44934502	PDIS = 2.3 Moderate irritant; erythema and edema at all test sites at one hour; erythema (grades 1 and 2) at 5/6 sites at 72 hours; irritation cleared by day 7	III	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated